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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 05242004

Application Number: 09/963,738
Filing Date: September 26, 2001
Appellant(s): MARUYAMA, NAOSUKE

Shawna Cannon Lemon
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 10, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-21 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

WO 98/53798	SHIMIZU ET AL	12-1998
US 3,852,421	KOYANAGI ET AL	12-1974
US 6,380,381 B1	OBARA	4-2002

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al (WO 98/53798) in view of Koyanagi (US Patent No. 3,852,421).

Appellant claims a base material for dry direct tableting, which is obtained by impregnating low-substituted hydroxypropyl cellulose with a sugar or a sugar alcohol and then drying it. Further limitations as seen in the dependent claims include the degree of compaction, the flowability index, the identity of the sugar or sugar alcohol, and the amount of the sugar or sugar alcohol.

The Shimizu et al patent discloses a solid preparation that comprises a water-soluble sugar alcohol that may be selected as sorbitol and erythritol (see abstract), which are set forth in instant Claims 5-8 and 17-20, and a low-substituted hydroxypropyl cellulose (see abstract) as indicated in instant Claims 1, 2 and 9-16. See page 10, lines 23-25 of the Shimizu et al patent wherein the dosage forms of the solid preparation are preferably tablets, which embraces the "dry direct tableting" indicated in instant Claims 1-20. On page 9, lines 14-17, the Shimizu et al patent discloses that the water-soluble sugar alcohol is in an amount of 5 to 97 weight parts, per 100 weight parts of the solid preparation, which covers the amount of 30 to 100% by weight based on the low-substituted hydroxypropyl cellulose that is set forth in instant Claims 9-16. See page 15, lines 15-18 of the Shimizu et al patent wherein the strength of the solid preparation is usually about 2 to 20 kg, which embraces the degree of compaction of 35% or greater that is set forth in instant Claim 2. The instant claims differ from the Shimizu et al patent by claiming that the base material is for dry direct tableting.

The Koyanagi et al patent, which discloses hydroxypropyl cellulose having a hydroxypropyl radical-substituted moles per glucose unit from 0.1 to 1.30 (see column 2, lines 22, 29 and 30), shows that tableting hydroxypropyl cellulose by dry and direct compression is well known in the art. See column 3, last paragraph of the Koyanagi et al patent wherein Example 1 indicates that the mixtures, which include low substituted hydroxypropyl cellulose, were tableted by a dry and direct compression method into tablets. The disclosure in the Koyanagi et al patent of the hydroxypropyl cellulose having a hydroxypropyl radical-substituted moles per glucose unit from 0.1 to 1.30 embraces low-substituted hydroxypropyl cellulose. The present of lactose in the composition with the hydroxpropyl cellulose (see Table 1) embraces the use of a sugar with the hydroxpropyl cellulose that is set forth in the instant claims.

The instant claims also differ from the Shimizu et al and Koyanagi et al patent by claiming that the base material has a flowability index of 60 or greater. Shimizu et al and Koyanagi et al do not disclose the flowability index of their products. However, since virtually all of the other characteristics of the product in the instant claims (such as the presence of low substituted hydroxypropyl cellulose and a sugar or sugar alcohol,

their concentration, degree of compaction, and their use for dry direct tableting) are set forth in the Shimizu et al and Koyanagi et al patents, the flowability index would be considered an inherent characteristic of the hydroxypropyl cellulose compositions of the Shimizu et al and Koyanagi et al patents. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Appellant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

It is noted that the instant claims are set forth in the form of product-by-process claims, which are considered product claims by the Office. Appellants are reminded that process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), supra; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc.* v. *United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981.

One of ordinary skill in this art would be motivated to combine the teachings of the Shimizu et al patent with the Koyanagi et al patent since both references disclose low-substituted hyroxypropyl cellulose compositions in the form of tablets.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the low substituted hydroxypropyl cellulose composition of the Shimizu et al patent for dry direct tableting in view of the recognition in the art, as evidence by the Koyanagi et al patent, that low substituted hydroxypropyl cellulose composition is excellent as a shaping agent and as a binder for forming tablets.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al in view of Koyanagi et al as applied to Claims 1-20 above, and further in view of Obara (US Patent No. 6,380,381).

Appellant claims a base material for dry direct tableting, which is obtained by impregnating low-substituted hydroxypropyl cellulose having a hydroxypropyl cellulose

content in the range from 5 to 16% by weight with a sugar or a sugar alcohol and then drying the product resulting therefrom. Additional limitations in dependent Claim 21 include the low-substituted hydroxypropyl cellulose in fibrous form.

The information discussed in the Shimizu et al and Koyanagi et al patents in the above rejection of Claims 1-20 is incorporated into the current rejection. The instant claim differs from the Shimizu et al patent and the Koyanagi et al patent by claiming that the low-substituted hydroxypropyl cellulose is in fibrous form.

The Obara patent shows that the use of low-substituted hydroxypropyl cellulose in fibrous form to prepare tablets is known in the art (see column 1, lines 27-29).

One of ordinary skill in this art would be motivated to combine the teachings of the Shimizu et al patent and the Koyanagi et al patent with the teachings of the Obara patent since all the references disclose low-substituted hyroxypropyl cellulose components as part of a composition in tablet form.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the low substituted hydroxypropyl cellulose composition of the Shimizu et al patent and Konyanagi et al patent for dry direct tableting in view of the recognition in the art, as evidence by the Obara patent, that low substituted hydroxypropyl cellulose in fibrous form serves to increase the hardness of tablets.

(11) Response to Argument

Appellant's arguments filed February 10, 2004 have been fully considered but they are not persuasive. The key passage that is used in the instant claims which is also exemplified in Applicants arguments is the low substituted hydroxypropyl cellulose is impregnated with a sugar or sugar alcohol. It appears that in order to determine the patentability of the instantly claimed invention, one would have to determine what the term impregnated means in the instantly claimed invention. No specific definition for impregnation is set forth in the instant specification. The only place in the specification wherein impregnation is discussed to some degree in the specification is set forth in the

paragraph located on page 6, line 23 to page 7, line 15, which is disclosed below for conveniency.

According to one preferred process for preparing this base material for dry direct tableting obtained by impregnating low-substituted hydroxypropyl cellulose with a sugar or a sugar alcohol and then drying it, a wet granular material is prepared by dry-blending low-substituted hydroxypropyl cellulose with a sugar or a sugar alcohol and then adding water to the resulting blend while agitating it, or by adding an aqueous solution of a sugar or a sugar alcohol to low-substituted hydroxypropyl cellulose while agitating it. Thereafter, the resulting granular material is dried in the usual manner, and may be pulverized and classified as required. Thus, the desired base material for dry direct tableting comprising low-substituted hydroxypropyl cellulose impregnated with a sugar or sugar alcohol can be obtained. In addition to the above-described agitation granulation process, this base material may also be prepared by fluidized bed granulation, spray drying and other suitable processes.

This discussion of impregnation in the specification is only a general discussion of the term. When only a general definition is set forth in an application for "impregnation" or related terms used in the claims, then the term is classified generically, wherein in the instant case, Class 427, Coating Processes is categorized. See class definition for Class 427, which is conveniently set forth below.

CLASS 427, COATING PROCESSES
CLASS DEFINITION
A. This is the generic class for applying or obtaining a coating on a surface. The coating may be hard or soft, permanent or transitory, supplied solely by extraneous materials or supplied wholly or in part by the base material.

B. This is the generic class for impregnating a base by causing a coating material to extend or penetrate into the base material, or into the interstices of a porous, cellular or foraminous material. (1) Throughout this class the term "base" or "substrate" refers to the surface upon which a coating is formed except in those instances in which a surface has been previously coated and a second coating is applied, in which case the initial surface is considered the base or substrate. In the case of laminated products the base or substrate is the surface upon which the coating is directly applied. (2) Throughout this class, the term "coating" is used in the generic sense to include both surface coating and impregnation.

C. This class also takes preparatory treatments of the base material, subsequent treatments of the coated base material and other ancillary

noncoating operations claimed, per se, processes limited to etching for making a base more compatible with, or adherent to, the coating wherein the base is the substrate (work) onto which a coating is applied are included, when there is no class which specifically provides therefor.

Without knowing the extent the impregnation of the sugar or sugar alcohol into the low-substituted hydroxypropyl cellulose, the generic definition of impregnation is applied in the examination of the claims as set forth in Class 427.

Appellant states that the Shimizu et al patent exemplifies the use of a fluidized bed granulator in the examples thereof and argues that employing a fluidized bed granulator enables the sugar alcohol to attach only to the surface of the low-substituted hydroxypropyl cellulose. This argument is not persuasive since there will inherently be some degree of penetration or absorption of the sugar alcohol - even using a fluidized bed granulator. See Appellant own specification on page 7, line 14, wherein it is stated that the base material thereof (which is the instantly claimed dry direct tableting base material) may also be prepared by fluidized bed granulation.

Appellant further argues against the rejection on the ground that impregnation of the low-substituted hydroxypropyl cellulose with a sugar or sugar alcohol results in a structurally different product. However, Appellant has not provided evidence that the instantly claimed sugar or sugar alcohol impregnated low-substituted hydroxypropyl cellulose is structurally different from the solid preparations and cellulose products of the Shimizu et al and Koyanagi et al patents.

On page 5, 3rd paragraph, Appellant argues that the Shimizu et al patent is limited to blending procedures using conventional blending techniques such as admixing, kneading, granulating, etc. and argues that these procedures produce products that are different from the instantly claimed process of impregnating low-substituted hydroxypropyl cellulose with a sugar alcohol. This argument is not persuasive since insufficient information is disclosed in the instant application that would patentably distinguish "impregnating" from other terms such as "kneading". An Examiner is required to give broad interpretation to terms during examination, when the terms have not been specifically defined in the application. The Class definition of

Class 427 is used by the Examiner to define "impregnation", which encompassed procedures such as "kneading".

On page 6, 2nd paragraph, Appellant argues that the missing recitations of the Shimizu et al patent are not supplied by the Koyanagi et al patent. This argument is not persuasive. The Koyanagi et al patent, which discloses hydroxypropyl cellulose having hydroxypropyl radical-substituted moles per glucose unit from 0.1 to 1.30 (see column 2, lines 22, 29 and 30), shows that tableting hydroxypropyl cellulose by dry and direct compression is well known in the art. See column 3, last paragraph of the Koyanagi et al patent wherein Example 1 discloses that the mixtures, which include low substituted hydroxypropyl cellulose, was tableted by a dry and direct compression method into tablets. The disclosure in the Koyanagi et al patent wherein the hydroxypropyl cellulose includes hydroxypropyl radical-substituted moles per glucose unit from 0.1 to 1.30 embraces the low-substituted hydroxypropyl cellulose of the instant claims. The presence of lactose in the composition with the hydroxpropyl cellulose (see Table 1) embraces the use of a sugar with the hydroxpropyl cellulose set forth in the instant claims.

In response to Appellant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Appellant submitted a Declaration Under 37 C.F.R. 1.132 by Naosuke Maruyama that was filed September 12, 2003. The declaration was not persuasive since the amount of low-substituted hydroxypropylcellulose and sugar alcohol recited in Comparative Example 2 of the declaration appears to be substantially different from the amount of alcohol disclosed in the instant claims, which the skilled artisan would expect to influence the final results set forth therein. The brief indicated that the results of the

comparative data set forth in the declaration show that the product provided by Shimizu et al has a lower flowability index compared to the base materials provide in Examples 1 and 4 of the present application. It is noted on page 9, 2nd paragraph and page 10, 1st paragraph of the Shimizu et al patent that the amount of sugar alcohol used is in an amount of 5 to 97 weight parts, per 100 weight parts of a solid preparation and the amount of low-substituted hydroxypropylcellulose is 3 to 50 weight parts, per 100 weight parts of a solid preparation. The ratio of the sugar alcohol and low substituted hydroxypropyl cellulose of the Shimizu et al patent is within range of the ratio of the sugar alcohol to low substituted hydroxypropyl cellulose of the instant claims. There is no reason why a comparison of the sugar alcohol/low-substituted hydroxypropyl cellulose composition of the Shimizu et al patent and of the instant claims using components of more similar ratios was not set forth in the declaration presented by Naosuke Maruyama. Hence, the Declaration by Naosuke Maruyama is not seen to be persuasive.

In response to Appellant's argument regarding the Declaration presented by Naosuke Maruyama that the references fail to show certain features of Appellant's invention, it is noted that the features upon which Appellant relies (i.e., binding power and disintegrability time of the sugar alcohol and hydroxypropyl cellulose composition) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellant further presented arguments over the rejection of Claim 21 as being unpatentable over the Shimizu et al patent in view of the Koyanagi et al patent as applied to Claims 1-20 above, and further in view of the Obara patent. The Obara patent is cited to show that the use of low-substituted hydroxypropyl cellulose in fibrous form to prepare tablets is known in the art. One of ordinary skill in this art would be motivated to combine the teachings of the Shimizu et al and Koyanagi et al patents with the teachings of the Obara patent since all the references disclose low-substituted hyroxypropyl cellulose components as part of a composition in tablet form.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the low substituted hydroxypropyl cellulose composition of the Shimizu et al and Konyanagi et al patent for dry direct tableting in view of the recognition in the art, as evidence by the Obara patent, that low substituted hydroxypropyl cellulose in fibrous form serves to increase the hardness of tablets. For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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May 27, 2004

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